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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/507,108	02/17/2000	Mary M. Swenson	54682 USA 6A	7637

32692 7590 10/28/2003

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EXAMINER

LEWIS, KIM M

ART UNIT	PAPER NUMBER
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3761

DATE MAILED: 10/28/2003

19

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/507,108

Applicant(s)

SWENSON, MARY M.

Examiner

Kim M. Lewis

Art Unit

3761

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 22 March 2002 and 30 August 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-35 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-35 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☒ Other: *Detailed Action*.

DETAILED ACTION

Summary

As indicated in the Advisory Action mailed 10/1/02, the finality of the Office Action mailed 5/6/02 has been withdrawn and prosecution of this application has been reopened in order to reconsider the Declaration filed under 37 CFR 1.132 and to consider Exhibits A and B.

Currently, claims 1-35 are pending in the application, of which, claims 3 and 24 were previously amended.

A substitute drawing of Figure 1 was filed with the Amendment of filed 3/25/02. The examiner has approved the drawing.

37 CFR 1.132 Declaration

The Declaration under 37 CFR 1.132 filed 3/220/02 is insufficient to overcome the rejection of claims 1-9, 11-16, 18, 19, 22-27, 29-32, 34 and 35 based upon Rawlings et al. applied under 35 USC 102 and claims 10, 17, 20, 21, 28 and 33 based upon Rawlings et al. in view of Ward applied under 35 USC 103 as set forth in the last and/or present Office action because: the declaration only presents evidence of the results of the Swell Test described on page 9 of the specification for two foams described in Rawlings et al., namely HYPOL 2000 and HYPOL 2002, not all those disclosed by Rawlings et al. Additionally, an independent third party did not complete the testing.

Art Unit: 3761

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-9, 11-16, 18, 19, 22-27, 29-32, 34 and 35a re rejected under 35 U.S.C. 102(b) as being anticipated by U.S. Patent No. 5,409,472 ("Rawlings et al.")

Prior to beginning claim analysis, the examiner wishes to point out that the specification on page 5, lines 31-22 recites the following:

"[p]referred foams are also substantially nonswellable. In this context, "substantially nonswellable" means that there is little or no increase in volume of the foam upon absorption of water or saline, and hence, exudate from a wound".

Then on page 6, lines 24-31, the specification recites:

"[e]xamples of suitable material for the absorbent, substantially nonswellable foams include synthetic organic polymers including, but not limited to: polyurethanes, carboxylated butadiene-styrene rubbers, polyesters, and polyacrylates. The polymeric foams can be made of one or more types of monomers (e.g. copolymers) or mixtures (e.g. blends) of polymers. Preferred foam materials are polyurethanes. A particularly preferred foam is a polyurethane, available under the trade designation POLYCRIL400 from Fulflex, Inc., Middleton, R.I."

In light of the above-recited paragraphs, Rawlings et al. anticipate the invention of claim 1 as presently claimed. More specifically, Rawlings et al. disclose a medical article in the form of an adhesive polymeric dressing comprising a liquid impervious, water-vapor permeable film material (col. 8, lines 65-66 and col. 12, lines 65-66) having directly bonded thereto an absorbent foam.

Art Unit: 3761

Rawlings et al. further disclose apt foams constructed from "polyurethane, carboxylated butadiene styrene rubber, polyacrylate or like foam. Such foams may be made of hydrophilic materials *per se* or may be treated to render them hydrophilic, for example, with surfactants" (col. 6, line 58-67). Similarly, the applicant on page 6, lines 24+ disclose the same absorbent foams.

Since the applicant fails to disclose in both the specification and claims anything that would chemically or physically alter the disclosed absorbent foams in order to render them nonswellable, the examiner contends that the nonswellable feature of the foams is an inherent characteristic of the foam. It then follows that the same foams disclosed by Rawlings et al. have the same inherent nonswellable characteristic., the same wet and dry MVTRs, would absorb the same amounts of NaCl, and would have the same increases in volume.

As regards claim 11, note col. 9, lines 5-20, which discloses the permeability of the film.

As regards claim 12, note col. 9, lines 47-48, which discloses the thickness of the film.

As regards claims 13 and 14, since the materials used in Rawlings et al. are the same and the applicant fails to claim anything that would chemically or physically alter the absorbent foam, the examiner contends the foam has the same characteristics.

As regards claims 15 and 16, note col. 6, lines 42-47 and lines 58-59, which discloses the type of foam used.

Art Unit: 3761

As regards claims 18 and 19, note Fig. 1, which discloses that the film extends beyond the periphery of the foam and an adhesive there around.

As regards claim 22, note col. 12, lines 38-45, which discloses how the foam is adhered to the film.

As regards claim 23, note the abstract, which discloses that the device is a wound dressing.

As regards claim 30, note the rejection of claim 1, *supra*.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 10, 17, 20, 21, 28 and 33 are rejected under 35 U.S.C. 103(a) as being unpatentable over Rawlings et al. in view of U.S. Patent No. 5,000,172 ("Ward").

Art Unit: 3761

As regards claims 10, 20, 28 and 33, Rawlings et al. fail to disclose that the film layer comprises one or more layers. However, Ward teaches it is known to construct backing layers (film layers) with additional film layers (nonwoven) for support. It would have been obvious to one having ordinary skill in the art to modify Rawlings et al. by constructing the film layer from one or more layers for additional support, as suggested by Ward.

As regards claim 17, Rawlings et al. fail to disclose graphics on the film material. However, Ward teaches it is known to provide graphics on the film layer of a bandage in order to monitor the size of a wound. It would have been obvious to one having ordinary skill in the art to modify Rawlings et al. with the addition of graphics on the film layer, as suggested by Ward, in order to monitor the size of a wound.

As regards claim 21, Ward discloses that the additional layer is adhesively bonded to the backing layer. Ward fails to teach the adhesive used is a fibrous adhesive. Absent a critical teaching and/or a showing of unexpected results derived from the use of a fibrous adhesive, the examiner contend that the type of adhesive used is an obvious design choice which does not patentably distinguish applicant's invention.

Response to Exhibit A

In response to Exhibit A, EP Patent Specification 0 171 268, the applicant argues that since the foams disclosed therein are swellable, then the same foams disclosed in Rawlings et al. are not necessarily substantially nonswellable. The examiner contends that just because the EP Patent Specification discloses foams similar to those disclosed

Art Unit: 3761

in Rawlings et al. that are swellable, that all of foams disclosed in Rawlings et al. are necessarily swellable. If what the applicant contends is valid, then shouldn't the foams of the instant invention also be swellable in light of the EP Patent Specification presented.

The examiner again reiterates that the applicant has neither stated in the specification nor the claims anything that would chemically or physically alter the absorbent foams in order to render them nonswellable. Therefore, no distinction can be made between the claimed nonswellable foams and the foams of Rawlings et al. since the disclosure of the foam materials are the same.

Perhaps, applicant's preferred foam, POLYCRIL™ foam, is chemically different than the disclosed polyurethane of Rawlings et al., and this difference amounts to the nonswellable property; however, this difference is not stated in the specification nor the claims.

The examiner cautions applicant in placing the trade name POLYCRIL™ in the claims since the addition of such may invoke a 112, 2nd paragraph rejection.

Response to Exhibit B

In response to applicant's arguments regarding Exhibit B, a product brochure from Dow Chemical Company including information regarding Hypol foams and gels, the examiner concedes that HYPOL may indeed affect the swellability of a product that incorporates them; however, it doesn't negate the fact that Rawlings et al. disclose the same materials disclosed by the applicant, e.g., carboxylated butadiene styrene rubber

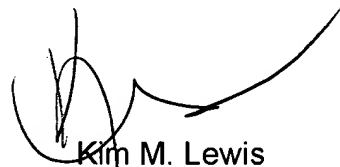
Art Unit: 3761

and polyacrylates, which have not been chemically or physically altered by the applicant or by Rawlings et al., and therefore must function the same and have the same properties.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kim M. Lewis whose telephone number is 703.308.1191. The examiner can normally be reached on Monday -Wednesday from 5:30 am to 4:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Weilun Lo can be reached on 703.308.1957. The fax phone numbers for the organization where this application or proceeding is assigned are 703.872.9306 for regular communications and 703.872.9306 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703.308.0858.



Kim M. Lewis
Primary Examiner
Art Unit 3761

kml
October 27, 2003